Common Questions about TCEQ Toxicity Factors and Protection of Human Health

What are AMCVs and ESLs?

Air Monitoring Comparison Values (AMCVs) and Effects Screening Levels (ESLs) are ambient air screening levels set to protect human health and welfare.

- AMCV is a collective term used to describe chemical-specific short- and long-term air concentrations used to evaluate air monitoring data that are set to protect human health and welfare.
- Health-based AMCVs are safe levels at which exposure is unlikely to result in adverse health
 effects. The TCEQ long-term AMCVs are similar to USEPA's inhalation Reference Concentrations
 (RfCs).
- ESLs are chemical-specific air concentrations set to protect human health and welfare and are
 used for permitting purposes. Health-based ESLs are values that are set 70% lower than the
 safe level, or AMCV. This additional buffer allows TCEQ to take into account exposure to
 chemicals from multiple sources in air permit reviews.
- AMCVs and ESLs are screening levels used to evaluate air monitoring data and air permits, respectively; they are not standards.
- The TCEQ's Toxicology Division calculates safe concentrations of chemicals in air, which are used in the permitting process to establish maximum emission rates. Maximum emission rates are then written into enforceable air permits.
- AMCVs are used by the TCEQ to determine if there is a potential concern, which would trigger a
 more in-depth review and focus of agency resources, such as in <u>Air Pollutant Watch List (APWL)</u>
 areas (https://www.tceq.texas.gov/permitting/air/apwl/apwl-index.html).
 - The APWL program has been particularly successful as there have been several areas/air contaminants removed from the APWL in the last few years. In an attempt to further promote transparent processes, all potential changes to the APWL are open for public comment. All state senators and representatives, whose districts are in these areas, are notified prior to any final change.

Are AMCVs and ESLs Health Protective?

Yes!

- TCEQ has developed state-of-the-science <u>Guidelines to Develop Toxicity Factors</u>,
 (https://www.tceq.texas.gov/toxicology/esl/guidelines/about.html), which have undergone a scientific peer review process and two rounds of public comment. We also <u>publish</u>
 (https://www.tceq.texas.gov/toxicology/faqs/tceq-publications) our work in the peer-reviewed scientific literature.
- ESLs and AMCVs are designed to prevent adverse health effects, including but not limited to cancer, respiratory diseases, and eye/respiratory irritation for all members of the population.
- These levels and values are set sufficiently below a level that would be expected to cause
 adverse effects, so that even when concentrations of a contaminant are somewhat above the
 ESL or ReV, adverse health effects would not be expected to occur. Therefore, an exceedance
 does not necessarily mean that an adverse health effect is expected, but rather, an in-depth
 review is needed.
- The TCEQ Guidelines follow standard scientific methods commonly used by other agencies, including the US EPA, to develop up-to-date toxicity factors.
- The TCEQ Guidelines were developed, in large part, in response to public demand for the most scientifically-defensible screening values available.
- Differences may exist between TCEQ screening levels and comparable values from other
 agencies due mainly to selection of more current studies, different datasets, evaluation of
 different exposure durations and interpretation of dose-response data, science policy, and the
 analytical and statistical tools used. There may also be differences in the methods used.
 Different values, regardless of whether they are higher or lower, are health protective and
 scientifically defensible.
- Development Support Documents (DSDs) outline the scientific basis and steps taken to develop toxicity factors. To be transparent, the DSDs are published on TCEQ's website: (https://www.tceq.texas.gov/toxicology/dsd/final.html).
- Values developed by TCEQ are used by other states and countries (e.g., Georgia, Louisiana, Michigan, North Carolina, Wisconsin, Minnesota, Belgium, Canada (Ontario, British Columbia, and Calgary), Israel, Netherlands, Taiwan, China, Australia, and Austria).

Why Have Some of the AMCVs and ESLs Changed?

Occasionally, when new scientific data and/or more recent methods become available, AMCVs and ESLs can change. The new values are scientifically valid and are generally more health-based. Updated values, regardless of whether they are higher or lower than the old values, are health-protective and scientifically defensible.

Benzene

- The 2007 long-term screening level for benzene (1.4 ppb) was derived under the 2006 TCEQ Guidelines to develop Effects Screening Levels, Reference Values, and Unit Risk Factors (RG-442).
- The TCEQ unit risk estimate used to develop the benzene long-term screening level falls within the range EPA has calculated, for which USEPA states "within which any calculated unit risk estimate would have **equal scientific validity**."
- The 2007 benzene Development Support Document (DSD),
 https://www.tceq.texas.gov/assets/public/implementation/tox/dsd/final/benzene 71-43-2 final 10-15-07.pdf, underwent public comment, and documents the most recent scientifically-defensible benzene values available.
- The old long-term screening level (1 ppb) for benzene was much less scientifically-based. It was derived by dividing an occupationally-acceptable level (OSHA TWA PEL of 1 ppm) by 1,000 (i.e., not through a state-of-the science dose-response assessment).
- The 2007 long-term screening level for benzene (1.4 ppb) is the product of using TCEQ's state-of-the-science Guidelines.

1,3-Butadiene

- The 2008 long-term screening level for 1,3-butadiene (9.1 ppb) resulted from the application of TCEQ's state-of-the-science Guidelines, as documented in the <u>DSD</u>, https://www.tceq.texas.gov/assets/public/implementation/tox/dsd/final/butadiene, 1-3- 106-99-0_final.pdf, (TCEQ has also published this information in a scientific journal, Risk Analysis).
- This screening level is based on an updated epidemiological study published in 2004; this study
 has more accurate, validated exposure estimates with additional years of data than the 19951996 epidemiological studies used by U.S. EPA.
- The 1,3-butadiene DSD underwent two public comment periods and an external scientific peer review; all the peer reviewers commented that the updated 2004 study was superior to the 1995-1996 studies.

- North Carolina has also utilized these updated data in calculating their acceptable ambient level (AAL) values.
- After conducting an extensive review, the Ontario Ministry of the Environment concluded that
 "Based on the inhalation unit risk estimates reported by Environment Canada/Health Canada,
 the US EPA, the states of North Carolina, and Texas,...The unit risk estimate of the State of Texas
 is considered to be the most appropriate URF since its derivation is based on an extensive risk
 analysis and a detailed peer review process."
- To be conservative, the TCEQ applied an age-dependent adjustment factor to account for susceptibility of children, as well as using multiple conservative assumptions, (i.e., the use of a linear, no threshold model; use of the 95% upper confidence limit instead of the central tendency value; data were restricted to the lower 95% of the exposure range; etc.).

Do Texans have more cancer or asthma than the rest of the Country?

No! Available data indicate that Texans have no more, or less, cancer and asthma than many other states, and the nation as a whole, even though Texas has more industry than any other state. (It is important to note, the environment is only one factor that may contribute to adverse health outcomes.)

 According to the Surveillance, Epidemiology, and End Results Program (SEER), statewide cancer incidence rates in Texas from 2007-2011 are amongst the lowest in the United States 2007-2011

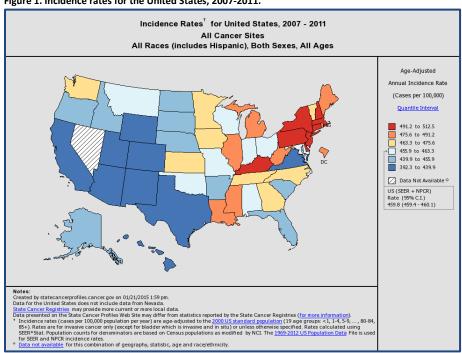
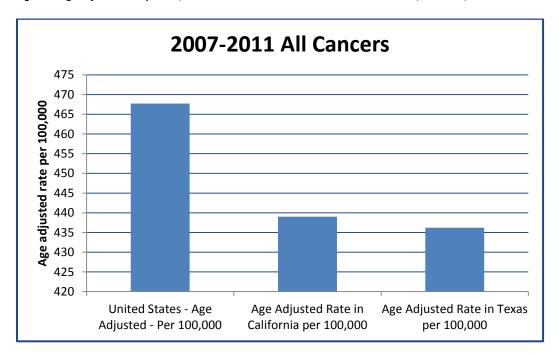


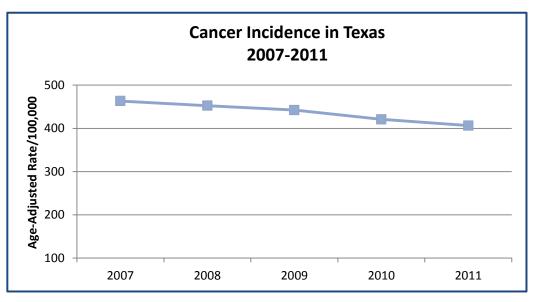
Figure 1. Incidence rates for the United States, 2007-2011.

Figure 2. Age-adjusted rates per 100,000 for all cancers for 2007-2011 in the United States, California, and Texas.

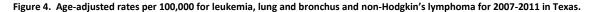


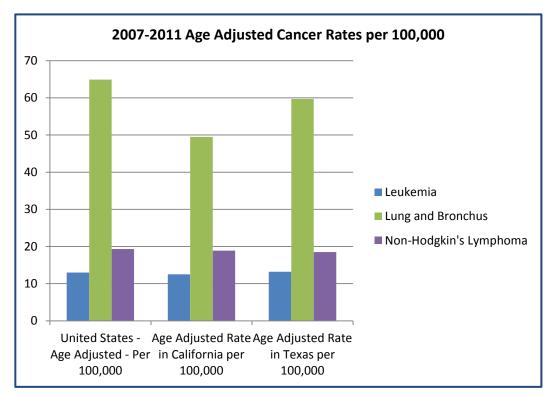
 According to the Texas Cancer Registry, statewide cancer incidence rates in Texas have demonstrated a slight decreasing trend from 2007-2011 (the most recent rates currently available).

Figure 3. Age-adjusted rates per 100,000 for all cancers for 2007-2011 in Texas.



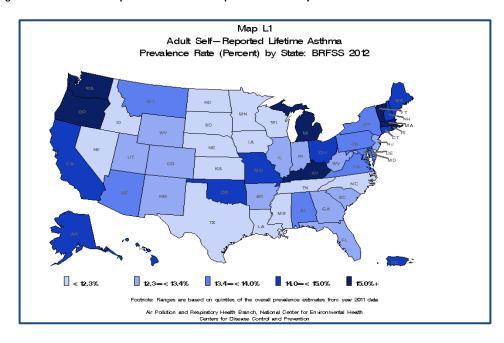
• From 2007-2011, Texas combined age adjusted cancer rates per 100,000 for leukemia, lung and bronchus (not adjusted for smoking), and non-Hodgkin's lymphoma were similar to California and the overall United States rates.





 According to the Air Pollution and Respiratory Health Branch of the CDC, 2012 Lifetime Asthma Prevalence rates in Texas are amongst the lowest in the United States.

Figure 5. 2012 Adult self-reported lifetime asthma prevalence rates by state.



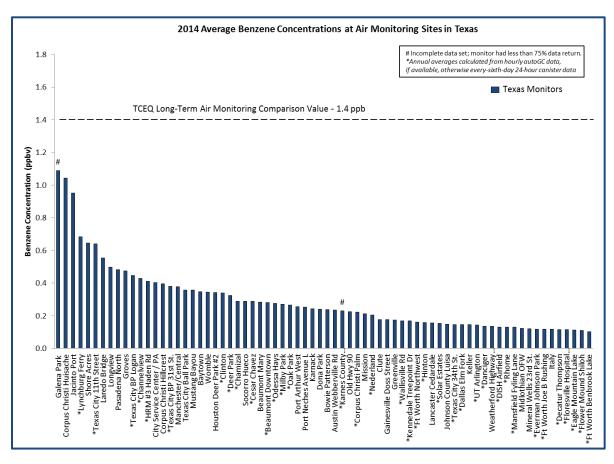
Has an Increase in AMCV/ESL Values Resulted in Increased Air Concentrations?

No!

Benzene

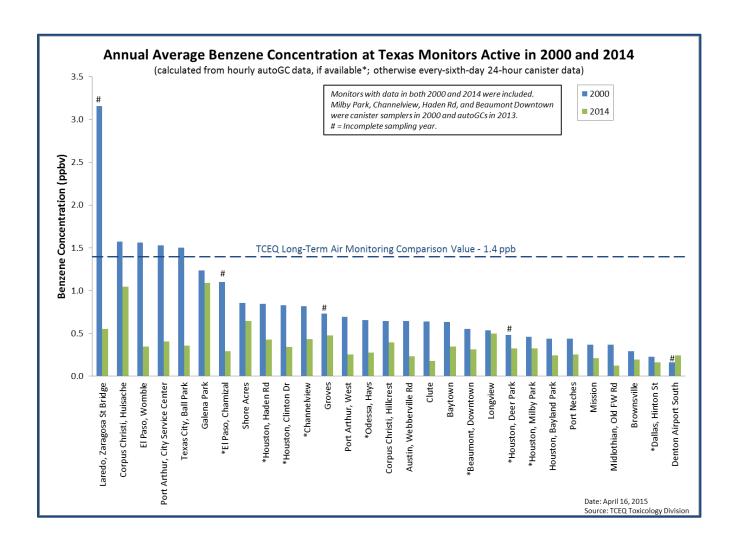
- Benzene is released into the air by a variety of sources (e.g., industry, automobiles, lawnmowers, etc.), and is one of the most widely monitored air toxics due to its ability to cause cancer (e.g., in workers occupationally exposed daily to very high levels).
- In 2014, all monitors in Texas had annual average benzene concentrations below the state's long-term AMCV.
- Since 2010, all monitors all monitors in Texas have had annual average benzene concentrations below the state's long-term AMCV.

Figure 6. Average benzene concentrations at monitoring sites in Texas in 2014.



Over 90 percent of the monitors operating from 2000-2014 (29 total across the state) showed a
decrease in benzene annual average concentrations. In 2014, all monitors in Texas had annual
average benzene concentrations below the state's long-term AMCV.

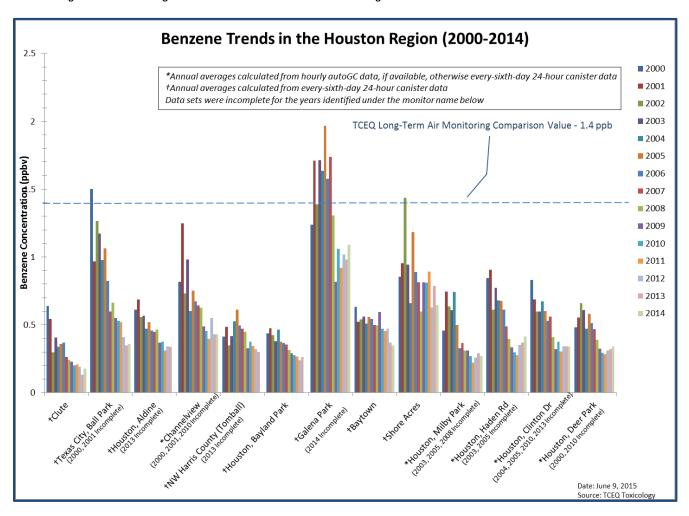
Figure 7. Annual average benzene concentration at Texas monitoring sites active in 2000 and 2014.



Benzene in Houston

- Houston is one of the most industrialized regions in the country.
- From 2000 to 2014, nearly 90 percent of the benzene monitors (10 total that were active in 2000 and 2014) in the Houston Region showed a decrease in annual average concentrations.
- In 2014, all monitors in the Houston Region had annual average benzene concentrations well below the AMCV.

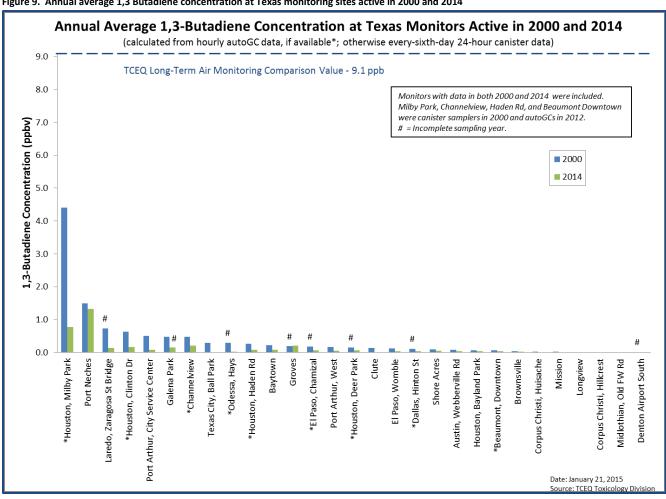
Figure 8. Annual average benzene concentration at Houston monitoring sites active in 2000 and 2013



1,3-butadiene

- 1,3-butadiene is frequently considered a chemical of concern by the public and risk assessors.
- From 2000 to 2014, nearly 76 percent of the 1,3-butadiene monitors (29 total active from 2000 to 2014) in Texas showed a decrease in annual average concentrations.
- Since 2000, all monitors in Texas have consistently shown annual average 1,3-butadiene concentrations many times below the state's long-term AMCV.

Figure 9. Annual average 1,3 Butadiene concentration at Texas monitoring sites active in 2000 and 2014



What is the Process for Changing AMCV and ESL Values?

As new scientific data and/or more recent methods become available, AMCVs and ESLs may change to reflect the latest available science.

- As part of this process, the public has the opportunity to submit comments on Development Support Documents (DSDs). Visit http://www.tceq.state.tx.us/toxicology/dsd/dsds_about.html/#how for information on how to submit comments.
- In addition, TCEQ welcomes submission of data and/or proposed revisions from anyone; all data and/or proposals received are evaluated based on their scientific and technical merit.
 Comments that increase the scientific and technical merit of the chemical-specific AMCVs or ESLs are incorporated.
- The TCEQ Toxicology listserv is provided as a service to keep the public informed of news and changes to our programs. For example, the listserv notifies environmental groups, academia, industry, and any other interested parties if a DSD has been posted for public comment.
- Toxicology e-mail alerts are a TCEQ service to keep the public informed of news and changes to our programs. To sign up to receive e-mail alerts related to the ESL List or the AMCV List, and other TCEQ Toxicology announcements, visit
 www.tceq.texas.gov/toxicology/announcements>.

What are External Experts Saying about Texas Guidelines?

Various other State and Federal agencies have contacted TCEQ to find out about our guideline levels, and have complimented our work as state of the science.

Wisconsin DNR Report to the Natural Resources Board: Silica Study (August 2011):

- "In addition to its non-cancer benchmarks, TCEQ is the only air agency in the US that has established a cancer-based health benchmark for ambient air exposures to crystalline silica."
- "Among the states surveyed, Texas has the most comprehensive approach to controlling silica emissions."

Ontario Ministry of the Environment Science Discussion Document on the Development of an Air Standard for 1,3-Butadiene (December 2008):

"The TCEQ has strengthened the risk assessment of the US EPA for 1,3-butadiene by
incorporating new data not available to the US EPA in 2002. With support from the US EPA, the
TCEQ has derived new and in-depth dose-response and statistical analyses for 1,3-butadiene."

- "Of the risk assessments and unit risk estimations conducted by these jurisdictions examined, the dose-response analyses and quantitative risk analyses conducted by the TCEQ and NCSAB are preferred over those conducted by the Environment Canada/Health Canada and the US EPA for the selection of improved exposure estimation by the former jurisdictions. The TECQ provided detailed supporting documentation for its risk analyses and unit risk derivation. The TCEQ evaluation has been intensively peer-reviewed by an independent scientific organization and provided the most up-to-date evaluation of the cancer risks from 1,3-butadiene exposures. The unit risk estimate derived by the NCSAB is in close agreement with that developed by the TCEQ and therefore lends credibility to the inhalation cancer risk estimate reported by the TCEQ."
- "Based on the inhalation unit risk estimates reported by Environment Canada/Health Canada, the US EPA, the states of North Carolina, and Texas, the risk-specific air concentrations, at an excess lifetime cancer risk of one in a million, are derived to be 0.17, 0.03, 1.28, and 2 μg/m³, respectively. The cancer risk estimates proposed by the states of Texas and North Carolina are considered appropriate for the derivation air standards for Ontario for the use of updated and more reliable exposure estimates, as compared with those used by Environment Canada/Health Canada and the US EPA. The unit risk estimate of the State of Texas is considered to be the most appropriate URF since its derivation is based on an extensive risk analysis and a detailed peer review process."

Peer Reviewer Comments on the Peer Review of the US EPA Technical Support Document Titled: Methods to Develop Inhalation Cancer Risk for Chromium and Nickel Compounds

- Of three independent reviewers, two suggested using the URE (unit risk estimate) derived by the
 TCEQ rather than the one derived by the Integrated Risk Information System (IRIS); the third
 author did not comment on alternative approaches.
 - "I would recommend using the TCEQ URE of 1.7 x 10-4 μ g/m³. The risk assessment leading to the derivation of this number was performed recently, included an updated and critical review of the literature, and appears to be comprehensive with an emphasis on health protection. One additional strength of the TCEQ evaluation is its inclusion of the Grimsrud et al., (2003) study where soluble nickel compounds, one of the major types found in the EGU emissions, were associated with elevated cancer incidence. It should also be noted that the TCEQ URE is quite similar to that derived by the CDHS (2.6 x 10-4 μ g/m³) and the EPA for nickel refinery dust (2.4 x 10-4 μ g/m³). The TCEQ, CDHS and EPA nickel refinery dust UREs could also be combined to derive a composite URE."
 - "Use the TCEQ URE of 2.64-4 per μg/m3 (smoking adjusted Relative Risk Estimate with a U.S. background rate). This approach: (1) uses human data for the risk estimate, (2) takes advantage of a nickel-exposed cohort (Grimsrud 20039) for which there are data on the prevalence of smoking."

Peer Reviewer Comments on 2012 update to TCEQ Guidelines to Develop Toxicity Factors

- All responding reviewers agreed that the TCEQ Guidance references the most current, valid, and generally accepted federal or state guidance documents or key papers.
 - "To the best of my knowledge, this guidance is complete and thorough, even exhaustive, in its coverage of relevant guidance on development of toxicity criteria available in the United States and Europe."
- All responding reviewers agreed that the TCEQ Guidelines clearly describe the approaches to be
 used by TCEQ, and provide rational for situations where different procedures are utilized rather
 than those recommended in referenced federal or state guidance.
 - "The approaches to be used by TCEQ are clearly described. The discussion of the reasons for deviating from other procedures was one of the highlights of these guidelines; I found the support for those deviations to be very well developed and presented."
 - "The guidance certainly does describe every conceivable method and provides well documented rationale for each. The draft document actually reads more like a textbook than a guidance document. I found very few deviations from Federal guidance, and none of major consequence."
 - "It provides the scientific basis for the determinations being made and guidelines to guide the writer in assessing safe levels of exposure. The emphasis is on a refreshing use of developing the values based upon the guidelines and an intelligent use of professional judgment."
- All responding reviewers agreed that the general approaches are consistent with accepted risk assessment methodologies.
 - "These procedures are mostly like others this reviewer is familiar with, although they are a bit more detailed and seem to have the potential to be especially useful for those less than familiar with risk assessment processes."

General Comments

o "The authors of this report are to be commended for the thoroughness, accuracy and usefulness instilled into this report. This reviewer was impressed that, for example, even reports that have not been adequately implemented by the originating Agency, such as EPA"s application of BW allometry for oral studies, use of data arrays, use of ten Berge models and Cn x T, have been cited, discussed accurately and implementation thoughtfully proposed. The point-by-point analysis and examples of the Supplemental Guidance and the in-depth checklists for conducting WOE for mutagenic origins of cancers are, in my judgment, more helpful and clearer than those offered by the originating agency. This reviewer further opines that risk assessors utilizing this guidance will finish with products

- that are more transparent and more internally consistent than they would be by attempting to apply much of the existing EPA quidances."
- "A Final Word: The authors really should speak with a book publisher about using this guidance as the basis for assembling a textbook to train risk assessors."

Peer Reviewer Comments on 2006 TCEQ Guidelines on Development of Effects Screening Levels, Reference Values, and Unit Risk Factors

- "In general, the panel thought that the document was based on the most current and relevant federal and state guidance. One panel member commended TCEQ on staying current because it is often difficult to keep contemporary with the state of the science and policy at U.S. EPA."
- "The panel evaluated how well the ESL document incorporated and interpreted U.S. EPA's 2005 cancer guidelines."
- "In general, panel members felt that the approaches described for mixtures assessment were appropriate."
- "Overall, the panel concluded that the document incorporates the most current and relevant federal and state guidance."

How qualified are TCEQ toxicologists to do their jobs?

Extremely!

- TCEQ's Toxicology staff consists of 9 Ph.D. and 5 master's-level scientists, including 3 certified by the American Board of Toxicology. Two are also OSHA HAZWOPER Certified.
- The Toxicology staff collectively represent over 150 years of scientific experience.
- TCEQ Toxicologists are active in several professional societies including: American Conference of Governmental Industrial Hygienists, American Public Health Association, the ARA Dose-Response Advisory Committee, the Alliance for Risk Assessment, Society for Risk Analysis (SRA), and the Society of Toxicology.
- The Toxicology Division has awarded multiple grants and have participated in several collaborative research projects:
 - Hillcrest Community Environmental Investigation A two-year environmental investigation of ambient air, soil, and groundwater designed in collaboration with the local community to address its concerns from neighboring petroleum refineries.
 (http://www.tceq.texas.gov/toxicology/research/hillcrest.html)

- Midlothian, TX Ambient Air Collection & Analytical Chemical Analysis A year-long ambient air monitoring study designed in collaboration with the local community to address their concerns from neighboring point sources, July 2010 (http://www.tceq.texas.gov/toxicology/research/midlothian.html).
- O Houston Exposure to Air Toxics (HEATS) Collaborative research effort between TCEQ (\$400K from USEPA grant awarded to TCEQ, \$476K from TCEQ), the Mickey Leland National Urban Air Toxics Research Center (\$275K), the Texas Environmental Research Consortium (\$50K), and East Harris County Manufacturer's Association (\$50K); Research grant awarded to University of Texas School of Public Health for a 2 year air toxics personal exposure study; October 2009 (http://www.tceq.texas.gov/toxicology/research/heats.html).
- Houston Air Toxics Biomarkers of Exposure Study Research grant (\$100K) awarded to Texas A&M University for a year-long study designed to examine the utility of biomarker concentrations as an indication of ambient exposure to compounds of concern, as well as correlate biomarker levels observed to levels measured in the ambient air, December 2009. (http://www.tceq.texas.gov/toxicology/research/hatbes.html).
- Air Pollutant Concentrations Near Texas Roadways Research grant (\$250K) awarded to University of Texas Department of Chemical Engineering to measure both gas and particle phase contaminants from four sites, with each site representing a different traffic scenario; August 2007 (http://www.tceq.texas.gov/toxicology/research/roadways.html).
- TCEQ Toxicologists often participate in national workshops, serve on expert panels and are often invited to present at well-respected conferences and events.
- Several TCEQ Toxicologists have received prestigious awards and honors throughout their careers.
- TCEQ Toxicologists have authored and co-authored research articles on a wide variety of toxicological subjects in a number of scientific journals. For a complete list, please visit: https://www.tceq.texas.gov/toxicology/faqs/tceq-publications